

Friday, May 15, 2020 10:00 A.M. - 11:30 A.M. (Virtual) Meeting Minutes

Welcome and Introductions

Dr. Perman gave opening remarks and reviewed the ground rules of a virtual meeting. He called the meeting to order and carried out roll-call to confirm attendance.

Board Members in Attendance

- Jay Perman, MD, Chancellor University System Maryland [Chair]
- Christopher P. Austin, MD, Director, National Center for Advancing Translational Sciences U.S. National Institutes of Health
- Richard A. Bendis, President and CEO BioHealth Innovation Inc.
- Jarrod Borkat, Vice President Corporate Strategy Emergent Biosolutions
- Theodore J. Olsen, President and CEO PathSensors, Inc.
- Sanjay K. Rai, PhD, Chief Academic Officer and Senior Vice President for Academic Affairs Montgomery College
- Bob Storey, Principal The MVR Company
- Frank F. Weichold, MD, PhD, Director, Critical Path and Regulatory Science Initiatives, Office of the Commissioner U.S. Food and Drug Administration
- Christy Wyskiel, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures Johns Hopkins University
- Kelly M. Schulz, Secretary Maryland Department of Commerce (Ex-Officio)
- Linda Singh, PhD, Interim Executive Director and CEO Maryland Technology Development Corporation (Ex-Officio)

Board Members not in Attendance

- William Hearl, PhD President and CEO Immunomic Therapeutics Inc.
- Wendy Perrow, CEO AsclepiX Therapeutics

Department of Commerce Attendees

- Ernesto Chanona, PhD Senior Manager, BioHealth & Life Sciences
- Ulyana Desiderio, PhD Director, BioHealth & Life Sciences
- Heather Gramm Senior Director, Strategic Industries & Entrepreneurship
- Connie Page Administrative Associate
- Signe Pringle Assistant Secretary Division of Business and Industry Sector Development

General Public Attendees

• J. Thomas Sadowski – Vice Chancellor for Economic Development, University System of Maryland

Dr. Perman introduced Ulyana Desiderio, the new Director of BioHealth and Life Sciences. He reminded everyone about the Board's charge to maintain Maryland's preeminence in the life sciences industry and gave an overview of the meeting's agenda.

Review and Acceptance of June 19, 2019 Meeting Minutes

Dr. Perman asked for feedback on the minutes of the June 19, 2019 LSAB meeting. Hearing none, he asked for a motion to approve the minutes which was made by Dr. Rai and seconded by Mr. Storey. The meeting minutes were approved unanimously.

Secretary of Commerce Update

Secretary Schulz welcomed everyone and thanked Dr. Perman and members of the Board for their continued service. She welcomed Ulyana Desiderio and thanked Ernesto Chanona for his leadership over the last ten months to keep the activities of Commerce's BioHealth team moving forward.

Secretary Schultz gave an overview of the State's response to the COVID-19 pandemic with the help of 13 advisory groups of stakeholders from key industry sectors. Commerce instituted two new grant and loan programs totaling up to \$125M to sustain and support Maryland's business community. Commerce brought in 150 volunteers to aid its current 200 employees and had to pivot quickly to establish procedures to review applications on an accelerated timeline. To date, 3,689 grant applications were approved for a total of \$36.2M and 238 loan applications were approved for \$10.48M in relief. The Secretary also gave an update on the \$5M COVID-19 Manufacturing Grant Fund to incentivize state's manufacturers to produce Personal Protective Equipment. To date, \$3.4M in grants were approved for 48 manufacturers.

Secretary Schulz welcomed insight and expertise the LSAB can provide to the state throughout the recovery process, and encouraged Board members to share thoughts, advice or concerns. The LSAB acts as liaison between the industry and the state and serves as the conduit for industry-specific issues to the Department of Commerce.

Update on 2019 Activities

Heather Gramm gave an update on the Maryland Medical Device Guidance, Prioritization, and Support (GPS) Initiative. The vision of this initiative was to drive medical device innovations to the marketplace through the de-risking of investments by incorporating the priority-needs of payers and providers. Proposed milestones for the initiative included a joint MOU between the FDA and Commerce; a list of high-priority needs from the payor, provider and patient communities in Maryland; and an eventual RFP from Maryland-based medical device developers to produce devices to address the high-priority needs. During the summer of 2019 discussions between Commerce and the FDA determined that an MOU was not feasible as envisioned and the team encountered challenges determining the next steps or identifying another mechanism by which the two parties could enter into an agreement. This was followed by the departure of the director, and no additional progress has been made on this effort. While this initiative presented

potential for accelerated development of medical devices, significant challenges remain and the framework as originally envisioned may not be achievable. If the LSAB decides to refocus on this effort, Ms. Gramm suggested that a subset of the Board work on identifying specific deliverables that can be presented to the entire Board for renewed consideration at a future date.

Ms. Gramm summarized the collaborations between the Department of Commerce and the National Institute of Standards and Technology (NIST) to increase technology transfer in the state in general and from the federal labs in particular. Most of the recommendations developed through this collaboration were published in the NIST green paper in April 2019. These collaborations also informed the legislative study on Small Business Innovation Research and Technology which was completed and submitted in January 2020 and distributed to the LSAB. One of the recommendations called for the creation of a state SBIR/STTR matching grant program. This legislation was successfully passed during this session but has been vetoed by the Governor as part of the pandemic recovery plan due to the fiscal impact.

Dr. Chanona gave an update on the Maryland Innovation and Technology (MINT) series focused on bringing together companies, academic researchers and federal labs to network and to collaborate. The next MINT event will focus on autoimmunity and it has been rescheduled for December 7, 2020.

In the discussion that followed, Mr. Storey described the increased momentum for medical devices and medical technologies in the state. There is robust innovation and clinical development, with opportunities for stabilizing the manufacturing supply chain. The FDA has been supportive of these efforts from the regulatory perspective. Mr. Storey shared ongoing efforts in recruiting medical technology innovators to the state, including bringing AdvaMed trade show to Baltimore.

Drs. Austin and Weichold signaled their support for the MINT series and volunteered to disseminate information about the next event across the NIH and FDA, respectively, if necessary.

Secretary Schulz commended Heather Gramm for her leadership during the BioHealth team transition. The LSAB members acknowledged Ms. Gramm's efforts and thanked her for her contributions.

Discussion on 2020 Activities

Dr. Perman opened a discussion on activities the Board could engage in the next few months. Mr. Olsen reminded the Board of its accomplishments in response to the recommendations it made for the 2017 BioHealth Acceleration Initiative. He suggested that a report card or a summary of achievements may be useful as the Board deliberates future activities. There was some discussion on the importance of developing strategic partnerships and collaborations to execute on the advice provided by the LSAB.

The Board discussed the multitude of federal funding opportunities becoming available to the life science industry in response to the pandemic and ways to ensure that Maryland companies and organizations are aware of these opportunities. Dr. Austin described Operation Warp Speed, a public-private partnership to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. He gave an example of the NIH Rapid Acceleration of Diagnostics (RADxSM) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. Mr. Borkat described the next several months as a window of opportunity for the Maryland scientific community to capitalize on the momentum and achieve meaningful milestones in a much shorter timeframe than usual. There was general agreement that this is an opportunity for Maryland to brand itself as a top life sciences cluster, with pandemic response serving as one recent example.

Dr. Singh and Mr. Bendis described the support TEDCO and BioHealth Innovation provide, respectively, to companies seeking federal funding, especially SBIR/STTR grants. There remains a need not only to raise awareness of these opportunities but, importantly, the need of technical assistance to companies for writing successful grants. Dr. Austin highlighted the importance of companies speaking with appropriate NIH Program Officers early and often to understand what reviewers are looking for in applications. Mr. Storey shared some success stories from LaunchPortTM, a Baltimore manufacturing accelerator, where start-ups and more mature companies are located in close proximity to benefit from expertise, mentorship and existing supply chain.

Dr. Rai brought up the importance of maintaining a highly trained life sciences talent pool and the discussed anticipated workforce needs across industry during pandemic response and recovery. Dr. Perman stated that institutions of higher education are committed to providing necessary training or retraining to expand the biotechnology and biomanufacturing workforce.

Closing Remarks

Dr. Perman thanked everyone for attending and actively participating in the meeting. He asked for any remarks from members of the public. Hearing none, Dr. Perman adjourned the meeting at 11:23 a.m.